REMARKS

Status of Claims and Amendment

Claims 36 and 37 have been amended. New claims 38-40 have been added. Claims 1-35 have been canceled.

Claim 36 has been amended to recite "an IC50 value between 1.5 nmol/l to 4.2 nmol/1." Support for the amendment to claim 36 may be found at least at page 41, lines 18-19 and page 57, line 26 of the specification.

Claim 37 has been amended to replace the article "a" with "an" and "activity" with "effect." Support for the amendment to claim 37 may be found at least at page 41, lines 1-20, page 42, line 20, page 43, line 13-14, page 58, lines 22-23, and Example 1 of the specification.

Support for new claims 38-40 may be found at least at page 33, page 39, lines 22-23, page 42, line 10 to page 43, line 2, page 43, line 23 to page 44, line 12, page 66, lines 16-22, page 70, lines 8-9, and Examples 2 and 5 of the specification.

No new matter is added.

Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 36-37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

The Office Action asserts that claim 36 is unclear because of the recitation "which compound has a ligand binding inhibitory effect". The Office Action asserts that it is unclear whether the ligand is added before or after the addition of the compound, and the range of the inhibitory effect is unclear. The Office Action suggests that the rejection may be obviated by reciting the limitations of claim 37 into claim 36.

The Office Action asserts claim 37 is improper for the recitation "a IC5 value" rather than "an IC50 value". The Examiner also asserts that there is insufficient antecedent basis of the limitation "the ligand binding inhibitory activity" in claim 37.

In response, Applicants note that "ligand binding inhibitory effect" is a term of art that is commonly recognized by those of ordinary skill in the pharmacological art to mean the effect of a compound on inhibiting or preventing another ligand from binding to the same binding site as shared by the compound. In this regard, one of ordinary skill in the art would understand from reading the specification, e.g., at page 41, 1st and 2nd paragraphs, and from common technical knowledge of the art, that the claimed compound's "ligand binding inhibitory effect" is based upon its ability to inhibit the binding of a labeled 45531.111 or 45523.111 antibody or isotype control thereof to a CCR5 expressing cell or membrane fraction. Also, it is clear from the specification that this inhibitory effect by the compound is determined by an IC50 value.

For instance, the present specification describes at page 41, lines 1-20 that the ligand binding inhibitory effects of CCR5 antagonists were shown using a binding test system of CCR5 endogenous ligand to CCR5. Also, Example 1 at pages 57-58 of the present specification shows the inhibitory effects of CCR5 antagonists for CCR5 and a radioisotope-labeled ligand. In each test system, the compound (CCR5 antagonist) and CCR5 are first bound and then the inhibitory effect is confirmed. Accordingly, with regard to "which compound has a ligand binding inhibitory effect", it is clear to those skilled in the relevant art that the compound is first added and then the ligand is added. Addition of the compound and ligand in such an order is commonly known and practiced in the pharmacological arts to evaluate the ligand binding inhibitory effect. That is, when the ligand binding inhibitory effect of an antagonist is evaluated, generally, the compound is first added and then the ligand is added. The reason is because when

the ligand is added prior to the compound, the ligand is bound to the receptor at that time so that the ligand binding inhibitory effect of the compound cannot be correctly evaluated. Thus, the phrase "which compound has a ligand binding inhibitory effect" would be clearly understood by those of ordinary skill in the pharmacological arts because one of ordinary skill in the relevant art would understand that to evalulate the ligand binding inhibitory effect, the compound is first added and then the compound is added.

Nevertheless, solely to advance prosecution of the present application, claim 36 has been amended as suggested by the Office Action to incorporate the IC50 value range of claim 37, i.e., to recite "an IC50 value between 1.5 nmol/l to 4.2 nmol/1." Claim 37 has been amended to replace "a" with "an".

Reconsideration and withdrawal of the rejection under § 112, second paragraph, is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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